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Applicants: Susan V. Cannon-Carlson et al.

U.S. Serial No.: 09/991,080

Group Art Unit: 1648

Examiner: Shanon A. Foley

Filed: November 16, 2001

Attorney Docket No.: JB01356

Location: TC 1600 Central File IIC10

Title: CHROMATOGRAPHIC PURIFICATION OF ADENO-ASSOCIATED
VIRUS (AAV)

Commissioner of Patents
Washington D.C. 20231

ATTN: Director of Examining Group 1648

PROTEST UNDER 37 C.F.R. 1.291(a)

Sir:

The protestor believes that it is improper to grant a patent based on the present application because of issues relating to possible violation of the duty of disclosure under 37 C.F.R. 1.56. The protestor notes that MPEP 1901.02(G) requires that issues related to disclosure "may be the subject of a protest under 37 C.F.R. 1.291(a)." In this case, Applicants failed to inform the Examiner that hydroxyapatite is a well-known material used in chromatography for the separation and purification of DNAs and viruses.

Alternatively, the protest is filed pursuant to MPEP 1901.02(A).

The protestor encloses a list of prior art references which the applicants might have known before the filing of this protest or will know by the filing and service of the present protest.

Moreover, these references include information material to the patentability of all pending claims. For example, WO97/08298, published on March 6, 1997, disclosed, in

claim 1, the use of ceramic hydroxyapatite to purify adeno-associated virus. WO97/08298 anticipates and/or render obvious all the pending claims of the present application.

Based on the disclosure of WO97/08298 and/or the references in the following list, the present application should be withdrawn by applicants or rejected by the USPTO on the merits because the use of hydroxyapatite as column filler for purifying adeno-virus and DNA were disclosed and/or claimed several times before Schering-Plough filed the present application.

WO97/08298; U.S.P.N. 5,496,926; U.S.P.N. 5,624,833; JP 11-347112; JP 11-332974; JP 11-323570; JP 11-322970; JP 11-322458; JP 318957; JP 11-318390; JP 11-308995; JP 11-292755; JP 11-267194; JP 11-267193; JP 61-49699; JP 11-156215; JP 11-157923; JP 11-158052; JP 11-171514; JP 11-171515; JP 11-171516; JP 11-171629; JP 60-143857; JP 11-171629; JP 11-171749; JP 11-197507; JP 11-201956; JP 61-146204; JP 11-206871; JP 11-207175; JP 11-209107; JP 11-209589; JP 11-217321; JP 11-217343; JP 11-222607; JP 11-222637; JP 11-228247; JP 11-228248; JP 11-228249; JP 11-228329; JP 11-240782; JP 11-240819; JP 11-255507; JP 11-255918; JP 11-256472; JP 11-018781; JP 11-028091; JP 11-028092; JP 11-033106; JP 11-079721; JP 11-140724; JP 62-233327; JP 10-287411; JP 10-265500; JP 10-259012; JP 10-236806; JP 10-155481; JP 10-130099; JP 10-090272; JP 10-057056; JP 08-333387; JP 08-268897; JP 08-188599; JP 08-071412; JP 08-071410; JP 08-040711; JP 08-034604; JP 07-291759; JP 07-173189; JP 07-146281; JP 07-143879; JP 07-327682; JP 08-168619; JP 09-169794; JP 2000-262280; JP 07-334773; JP 63-263093; JP 63-042687; and JP 2000-023668.

There are so many prior art references in this area and it is impossible to list all of them in one protest. However, protestor believes that this partial list of references is sufficient to anticipate and/or render obvious all the pending claims of the present application. Moreover, protestor reserves the rights to file further protests in the present application if it is not withdrawn or all the claims rejected by the USPTO.

As stated in MPEP 1901.02(G) "Protests raising fraud or other inequitable conduct issues will be entered in the application file, generally without comment on those issues. 37 C.F.R. 1.291(b)." If the applicants agree with the protestor's position, they are

expected to withdraw the present application. Alternatively, they should submit copies of relevant references and their translations to the PTO for consideration as it would be unfair to the examiner, the protestor and the public if applicants do not have to fulfill its duty of candor. Moreover, it is in Applicants' own interests to do so.

This protest is being filed anonymously because (1) MPEP 1901.01 states that "37 C.F.R. 1.291 does not require that the principal be identified," and (2) the protestor is not allowed any further participation in the examination process.

The protestor hereby certifies that a copy of the protest is mailed, via first class mail postage prepaid to:

Shering-Plough Corporation
Patent Department (K-6-1, 1990)
2000 Galloping Hill Road
Kenilworth, NJ 07033-0530

In addition, two copies of the protest are included herein. Please forward a copy to **Shering-Plough** if it does not receive its copy.

Protestor hereby certifies that protests against Schering-Plough's patent applications **WILL CONTINUE INDEFINITELY** in order to counter Schering-Plough's over-reaching behavior in seeking patent protection to subject matter that is already in the public domain.

Respectfully submitted,

Protestor

Dated: September 9, 2002